IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
BECKLEY

United States of America *et al.*,
ex rel. Steven May and
Angela Radcliffe,

Plaintiffs,

v.

Civil Action No. 5:10-1423
(Honorable Irene C. Berger)

Purdue Pharma L.P. and Purdue
Pharma, Inc.,

Defendants.

DEFENDANTS PURDUE PHARMA L.P. AND PURDUE PHARMA INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

This case is entirely recycled from a previous case, reflecting an effort to circumvent a prior judgment on the same allegations with a new case in a new forum. *See U.S. ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766 (W.D. Va. 2008); 2009 WL 161003 (W.D. Va. Jan. 25, 2009); 600 F.3d 319 (4th Cir. 2010); *cert. denied*, 131 S. Ct. 477 (2010).

The prior *qui tam* action was filed by Mark Radcliffe, husband of Angela Radcliffe and former supervisor of Steven May, who was represented by the same lawyers that are now before this Court. Like the present case, the prior action alleged that false claims were made to the government based on Purdue's statements about the relative potency ("equianalgesic ratio") and cost of OxyContin and MS Contin. The district court dismissed the prior case with prejudice on the ground that the third and fourth amended complaints failed to satisfy Fed. R. Civ. P. 9(b). At the government's request, the Fourth Circuit affirmed the dismissal on the alternative ground that the action was barred by a release Mark Radcliffe signed when he left Purdue. The Fourth Circuit emphasized that public policy favored dismissal because the government had been independently investigating Purdue's statements regarding the relative potency and cost of OxyContin and MS Contin well before Mark Radcliffe purported to bring them to the government's attention. The Supreme Court denied certiorari, and relators Steven May and Angela Radcliffe filed this identical suit in this new forum shortly thereafter.

The Court should dismiss this case, with prejudice, for each of the following reasons.

First, dismissal is required under principles of *res judicata* because the prior judgment on the merits precludes re-litigation of the same claims here.

Second, the public disclosure bar of the False Claims Act ("FCA"), 31 U.S.C. § 3730(e)(4), requires dismissal because relators' allegations are *identical* to those made in the prior action (which followed the government's independent investigation of the same

allegations) and relators cannot qualify as "original sources." This latest suit is "a classic example of the opportunistic litigation that the public disclosure bar is designed to discourage." *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 131 S. Ct. 1885, 1894 (2011) (internal quotation marks omitted).

Third, the complaint fails to satisfy either the heightened pleading standards of Fed. R. Civ. P. 9(b) or the more basic pleading requirements of Fed. R. Civ. P. 8 as construed by the Supreme Court in *Twombly* and *Iqbal*. The allegations are entirely conclusory and fail to allege facts supporting either the materiality or causation elements of an FCA violation.

Fourth, even if the Court were to allow this action to proceed, all but a handful of the hypothetical claims would be barred by the FCA's six-year statute of limitations, 31 U.S.C. § 3731(b)(1). Claims from December 30, 2004 and earlier are time-barred, and relator May left Purdue on January 1, 2005 (Compl. ¶ 23) and does not identify any claims submitted after that day—nor assert any direct knowledge of Purdue whatsoever after that day. His allegation that Purdue's marketing caused false claims to be submitted to the government within the statutory period is entirely conclusory—and therefore insufficient under federal pleading standards.

Finally, the state claims suffer from the same defects as the federal claims. The Court should either decline to exercise supplemental jurisdiction over them or dismiss them outright.

BACKGROUND

A. The Mark Radcliffe Action (*Qui Tam I*)

Mark Radcliffe, a former Purdue sales representative, filed a *qui tam* action ("*Qui Tam I*") against Purdue on September 27, 2005. *U.S. ex rel. Radcliffe v. Purdue Pharma L.P.*, No. 1:05-cv-00089 (W.D. Va.). He was represented by the same counsel as now represent the

current relators.[1] Mark Radcliffe made *identical* allegations to those made here:

- "Defendant asserted … that it took only one milligram of OxyContin to give the same pain relief as two milligrams of MS Contin. Defendant claimed that, despite OxyContin's higher per milligram cost, OxyContin was cheaper than MS Contin for the same measure of pain relief; in other words, that OxyContin's equianalgesic cost was less." *Qui Tam 1* 4th Am. Compl. ¶ 11.[2]

- "Purdue represented that one milligram of OxyContin would give the same pain relief as two milligrams of the benchmark, MS Contin. Purdue then represented that, despite OxyContin's higher per milligram cost, OxyContin was cheaper than MS Contin when they were measured based on the pain relief they provided; thus, the equianalgesic cost of OxyContin was less." Compl. ¶ 12.[3]

Purdue moved to dismiss *Qui Tam 1* on multiple grounds, including: lack of subject-matter jurisdiction because Radcliffe's allegations already had been publicly disclosed; failure to satisfy Rule 9(b); Radcliffe had released his claims; and there could be no FCA liability with respect to a legitimate scientific dispute over the relative potency of OxyContin and MS Contin.[4]

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[1] *See* Mot. to Dismiss Ex. 1, p. 3 (*Qui Tam 1* Docket sheet). In reviewing a motion to dismiss, courts may take judicial notice of matters of public record. *Sec'y of State for Defence v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007). Courts may also consider documents attached to a motion to dismiss "so long as they are integral to the complaint and authentic." *Id.*

[2] *See* Mot. to Dismiss Ex. 2 (Mark Radcliffe's Fourth Amended Complaint).

[3] *See* Mot. to Dismiss Ex. 3 comparing *Qui Tam 1* and *2* allegations.

[4] *See* Defendants' Motion to Dismiss Relator's Third Amended Complaint, 1:05-cv-00089, 6-7 (Oct. 2, 2007, Dkt. #43). In support of its motion to dismiss, Purdue provided the court with numerous articles from scientific and medical journals, which reflected an ongoing debate among scientists about the equianalgesic ratio of OxyContin and MS Contin. Certain scientists supported a 2:1 ratio (the ratio reflected on the package insert approved by the U.S. Food and Drug Administration), while other scientists believed the ratio was less than 2:1. *See id.* at 4-10.

Because claims cannot be "false" under the FCA where they are predicated on a scientific dispute, s*ee, e.g., Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 733 (7th Cir. 1999) (the court has rejected the notion that "taking one side of a medical or scientific dispute is 'fraud'"), Purdue argued that *Qui Tam 1* was based on one side of a legitimate scientific dispute and had to be dismissed. Ultimately, Purdue reserved the argument as a basis for summary judgment. *See* Defendants' Reply in Support of Motion to Dismiss Relator's Third Amended Complaint, 1:05-cv-00089, 35-36 (Dec. 21, 2007, Dkt. #61). Although this issue was not resolved (because the case was dismissed), the district court observed that the articles "suggest legitimate scientific debate and disagreement regarding the correct equianalgesic ratio, rather than any fraudulent intent on the part of Purdue." 582 F. Supp. 2d at 773.

The district court dismissed on the basis that Radcliffe had failed to satisfy Fed. R. Civ. P. 9(b). Specifically, the court determined that the third amended complaint failed to "describe even a single instance in which a physician was influenced to prescribe OxyContin based on Purdue's [alleged] misrepresentations, and where a claim for payment was made by the pharmacist to the government." 582 F. Supp. 2d at 784. Radcliffe was given a chance to amend, but his fourth amended complaint—which was substantially more detailed than the current complaint—failed to overcome that defect as well. Accordingly, the court dismissed the case with prejudice. *See* 2009 WL 161003 (W.D. Va. Jan. 25, 2009). As found by the court, the only specific allegations that addressed the required nexus between Purdue's representations and any decision to prescribe OxyContin were outside the FCA's six-year statutory limitations period. *See* 2009 WL 161003 (W.D. Va. Jan. 25, 2009). This defect was fatal to the complaint, and the court accordingly dismissed the case with prejudice. *Id.* at *1.

The Fourth Circuit affirmed the dismissal on the alternative ground—favored by the government, which appeared as *amicus curiae* in support of dismissal—that Mark Radcliffe had released his claims against Purdue. The Fourth Circuit held that public policy favored enforcing the release because the government had learned the substance of Radcliffe's allegations through its own comprehensive investigation of Purdue; allowing Radcliffe to serve as a *qui tam* relator would therefore serve no purpose: "[W]hen, as in this case, the government was aware, prior to the filing of the *qui tam* action, of the fraudulent conduct represented by the relator's allegations, the public interest has been served, and the Release should be enforced." 600 F.3d at 332-333.[5] As detailed by the district court, the government's investigation had begun to focus on the very same issues as alleged in *Qui Tam 1* through document requests and witness interviews in June

[5] The court of appeals did not address the Rule 9(b) dismissal. 600 F.3d at 322 n.2.

and July 2005, well before Mark Radcliffe filed his case. *See* 582 F. Supp. 2d at 775.[6]

Radcliffe's petition for certiorari was denied on October 12, 2010. 131 S. Ct. 477 (2010).

B. The Steven May and Angela Radcliffe Action (*Qui Tam 2*)

Relator Steven May left Purdue on January 1, 2005—six years before filing this action—and relator Angela Radcliffe never worked for Purdue. Compl. ¶¶ 2-3, 23. Their complaint, filed December 30, 2010, makes the same allegations as presented in *Qui Tam 1*. *See supra* Background Section A. Relators baldly allege that "they did not derive their allegations … from public disclosures and, in any case, Steven May is an original source, as defined in section 3730(e)(4) of the FCA, of the information on which the allegations contained herein are based." Compl. ¶ 1. The complaint provides no factual support for these conclusory assertions, notwithstanding relators' burden to do so. *See U.S. ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 348-349 (4th Cir. 2009).

As in *Qui Tam 1*, the federal and state governments declined to intervene.

ARGUMENT

I. DISMISSAL IS REQUIRED UNDER PRINCIPLES OF *RES JUDICATA*

Res judicata requires dismissal of this case. *Res judicata* applies where there is: (1) "a final judgment on the merits in a prior suit;" (2) "an identity of the cause of action in both the earlier and the later suit;" and (3) "an identity of parties or their privies in the two suits." *Pueschel v. U.S.*, 369 F.3d 345, 354-355 (4th Cir. 2004). Here, all three elements are satisfied.

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[6] The Fourth Circuit explained the government's investigation as follows: "According to a declaration executed by an Assistant United States Attorney, 'one area of investigation concern[ed] whether Purdue falsely marketed OxyContin as being twice as potent as morphine and, accordingly, less expensive than MSContin.' In the same declaration, the Assistant United States Attorney stated that 'the 2:1 comparison of OxyContin to MSContin [sic][wa]s one of the areas under investigation. … Beginning in 2002 and continuing for the next several years, the government sought millions of documents from Purdue and conducted hundreds of interviews, some of which pertained to the relative potency and cost of OxyContin and MS Contin.'" 600 F.3d at 322-323 (quoting 582 F. Supp. 2d at 775).

First, *Qui Tam 1* was dismissed with prejudice. 2009 WL 161003, at *1-*2; *see also* 600 F.3d at 333. Dismissal for failure to state a claim under Rule 12(b)(6) constitutes a "judgment on the merits" for *res judicata* purposes. *See U.S. ex rel. Folliard v. Synnex Corp.*, 798 F. Supp. 2d 66, 77 (D.D.C. 2011) (applying *res judicata* as to claims against Hewlett-Packard based on the dismissal of *U.S. ex rel. Folliard v. Hewlett-Packard Co.*, 272 F.R.D. 31, 36 (D.D.C. 2011), which was dismissed with prejudice "because Folliard has not—and in all likelihood, cannot—allege the facts required to state a claim under Rule 9(b)"); *see also Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 399 n.3 (1981); *Micklus v. Greer*, 705 F.2d 314, 317 (8th Cir. 1983). Second, the causes of action in the two cases are identical. *See supra* Background. Third, *Qui Tam 1* was brought on behalf of the United States as the real party in interest. Accordingly, both the United States and any other relators seeking to allege identical claims are bound by its judgment. *See U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009) ("If [relator] had litigated a qui tam action to the gills and lost, neither another relator nor the United States could start afresh."); *see also U.S. ex rel. Eisenstein v. City of N.Y.*, 129 S. Ct. 2230, 2236 (2009) ("[T]he United States is bound by the judgment in all FCA actions regardless of its participation in the case."). Dismissal is therefore required.

II. THE PUBLIC DISCLOSURE BAR OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3730(e)(4), REQUIRES DISMISSAL OF THIS ACTION

The public disclosure bar of the FCA also requires dismissal of this case, which follows not only the prior litigation (and the press it generated) about identical allegations, but also the government's independent investigation into those allegations. The purpose of the FCA's *qui tam* provision is to alert the government to undiscovered fraud, not to allow private litigants to piggyback off the government's investigations or other relators' work. Allowing this case to proceed would disturb the balance Congress struck "between encouraging private persons to root

out fraud and stifling parasitic lawsuits." *Graham County Soil & Water Conserv. Dist. v. U.S. ex rel. Wilson*, 130 S. Ct 1396, 1407 (2010). As the Fourth Circuit noted, Congress specifically intended to foreclose suits where relators, "rather than bringing to light independently-discovered information of fraud, simply feed off of previous disclosures of government fraud." *U.S. ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1347 (4th Cir. 1994).

Relators' recycled fraud allegations can hardly be described as "root[ing] out" undiscovered fraud, where the government participated in *Qui Tam 1* and confirmed in court that it already had been independently investigating the relative potency issues underlying these cases. As the government told the Fourth Circuit: "There is no dispute that, when the qui tam complaint in [*Qui Tam 1*] was filed, the government had for years been comprehensively investigating Purdue Pharma's OxyContin marketing practices—the same basic conduct that formed the basis of the relator's qui tam complaint." U.S. Amicus Br. 15-16, Nos. 09-1202, 09-1244 (4th Cir.); *see also id.* at 3 ("[T]he relator's allegations of fraud were disclosed to the government independent of the filing of the qui tam action[.]").

Congress amended the public disclosure bar in March 2010. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 901-902. While courts have yet to apply this new statute to cases such as this one,[7] Purdue believes the amended statute applies because the case was filed after the amendments took effect and, as relevant here, the amendments clarify the analysis courts must undertake when the allegations underlying a *qui tam*

[7] *Cf. Graham County Soil & Water Conserv. Dist.*, 130 S. Ct. at 1401 n.1 (2010 amendments not retroactive to cases filed before the amendments' effective date); *Schindler Elevator Corp. v. U.S. ex rel. v. Kirk*, 131 S. Ct. 1885, 1889 n.1 (2011) (same); *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 949-950 (1997) (1986 amendment to public disclosure bar not retroactive to pre-amendment claims, because, *inter alia*, retroactive application would remove a defense previously available or effectively create a new cause of action).

case were publicly disclosed before the case was filed. Dismissal, however, is warranted under either version of the statute.

A. Dismissal Under the Current Public Disclosure Bar

As of March 2010, the FCA requires courts to dismiss *qui tam* actions where "substantially the same allegations" have been publicly disclosed, unless the relator qualifies as an "original source." 31 U.S.C. § 3730(e)(4). Where the bar applies, dismissal is mandatory. *See id.* ("The court *shall dismiss*..." (emphasis added)). Relators cannot overcome the plain language of the public disclosure bar; dismissal is therefore required.

First, "substantially the same allegations" as alleged here have been publicly disclosed in three qualifying sources. They were disclosed in *Qui Tam 1*.[8] They were also disclosed in the government's investigation of Purdue's marketing of OxyContin.[9] And they were disclosed in press stories from 2008-2010.[10] These are indisputably public disclosures under the FCA. *See* 31 U.S.C. § 3730(e)(4)(A)(i) (covering disclosures in "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party"), (ii) (covering disclosures in "a ... Federal ... investigation"), & (iii) (covering disclosures through "the news media").

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[8] *See* Mot. to Dismiss Ex. 3; *see generally* 582 F. Supp. 2d at 769 (summarizing allegations).

[9] As the district court in the prior action explained (citing a sealed declaration filed by the government), the government had already been conducting an investigation into the very same allegations before *Qui Tam* 1 was filed. *See* 582 F. Supp. 2d at 775; *supra* n.5. Notably, after its exhaustive investigation, the government neither intervened in *Qui Tam 1* nor took any action against Purdue whatsoever with respect to these allegations.

[10] *See e.g.*, Ryan Davis, *Qui Tam Suit Over OxyContin a No-Go: Judge* (Oct. 16, 2008) ("[Mark Radcliffe] alleged that the company produced literature, instructed its sales representatives to claim, and otherwise communicated to the public that OxyContin was twice as potent as it actually is."); Nick Brown, *Qui Tam Relator Barred From Suing Purdue: 4th Cir.* (March 24, 2010) ("[Mark] Radcliffe sued the company in 2005, accusing it of violating the False Claims Act by falsely marketing OxyContin as twice as potent—and therefore cheaper per dose—than its predecessor, MS Contin."). Copies of these articles are attached to the Mot. to Dismiss as Exhibits 4 & 5.

Second, relators cannot qualify as "original sources" because they *neither*: (i) voluntarily disclosed the information underlying their case to the government prior to the filing of *Qui Tam 1*, *nor* (ii) possess knowledge that is "independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). As to Angela Radcliffe, the Complaint does not even allege that she is an original source or has any direct knowledge, and the court need not consider her status further. As to Steven May, the Complaint fails to allege that he provided *any* information to the government, and the complaint contains no material information beyond what had already been disclosed to the government by virtue of the prior action, the surrounding press, and the government's own multi-year investigation. Moreover, May left Purdue on January 1, 2005—nine months before *Qui Tam 1* was filed and *six years* before this action was filed—depriving him of any "insider" status that might have positioned him to add to the public store of information not already covered in *Qui Tam 1*.[11] *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 475 (2007) (relator could not qualify as original source with respect to violations that occurred after he left the defendant's employment, because relator did not have direct knowledge of the subsequent violation).[12]

B. Dismissal Under the Pre-Amendment Public Disclosure Bar

The suit also would be barred under the prior version of the statute, which deprived courts of jurisdiction over suits "based upon the public disclosure of allegations or transactions in

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[11] Mark Radcliffe's tenure at Purdue covered *all* of Steven May's time at the company. *Compare* 582 F. Supp. 2d at 774, 775 (Mark Radcliffe employed from 1996 to August 2005), *with* Compl. ¶¶ 19, 23 (Steven May employed from November 1999 to January 1, 2005).

[12] *Rockwell* addressed the disposal of toxic waste in the form of solidified "pondcrete." In holding that the relator did not qualify as an original source with respect to pondcrete failures that arose after he left Rockwell, the Supreme Court explained: "Because [relator] was no longer employed by Rockwell at the time, he did not know that the pondcrete was insolid; … he did not know that Rockwell would fail to remedy the defect; he did not know that the insolid pondcrete leaked while being stored onsite; and, of course, he did not know that Rockwell made false statements to the Government regarding pondcrete storage." 549 U.S. at 475.

a criminal, civil, or administrative hearing, … or investigation, or from the news media," unless the relator qualifies as an original source. 31 U.S.C. § 3730(e)(4)(A) (as previously codified). Relators cannot meet their burden of proving that: (a) the allegations underpinning their case were not based upon the public disclosures surrounding the prior suit or investigation, or (b) they were the original sources of the information on which the allegations are based *and* voluntarily provided that information to the government as required by statute. *See Vuyyuru*, 555 F.3d at 348-349 (describing these as "separate and distinct burden[s]" the relator must meet to overcome a defendant's challenge to the court's jurisdiction). The Fourth Circuit has made clear that the bar encompasses actions "even partly based upon" public disclosures." *Id.* at 351.

The unusual circumstances—the identity of the allegations in *Qui Tam* 1 and this action; the close relationships among the relators; that Angela Radcliffe never worked at Purdue and that Steven May did not work at Purdue during the six years preceding this action; and the identity of counsel in *Qui Tam* 1 and this action—make it implausible that this action was not *at least partially* based on the prior litigation (and thus relators cannot carry their jurisdictional burden). As a purely practical matter, counsel could not plausibly have prepared the present complaint without relying to some degree on their knowledge of the prior case. *Cf. U.S. ex rel. Lopez v. Strayer Educ., Inc.*, 698 F. Supp. 2d 633, 640 n.6, 643 (E.D. Va. 2010) (dismissing FCA case because relator lacked personal knowledge of the core facts and suggesting that relator's counsel derived allegations from a complaint he filed in another action); *Schultz v. DeVry Inc.*, No. 07 C 5425, 2009 WL 562286, at *3-*4 (N.D. Ill. Mar. 4, 2009) (similar).[13] Further, where, as here, a relator's allegations bear "remarkable similarities" to newspaper articles published before the suit was filed and for which the relator was not a source, courts have not hesitated to dismiss

[13] As reflected in Mot. to Dismiss Ex. 3, numerous allegations in the present complaint were apparently taken verbatim from those in the Fourth Amended Complaint in *Qui Tam 1*, while others have been edited slightly.

complaints on public-disclosure grounds. *See Vuyyuru*, 555 F.3d at 350-351. In *Vuyyuru*, the Fourth Circuit expressly found affirmance was warranted "even under the best-case scenario for [the relator], which is that [only] *some* of the allegations in his [complaint] were not based upon a public disclosure." *Id.* at 351.

Relators do not allege facts sufficient to establish that they were original sources (and could not prove by a preponderance of the evidence that they were). *See* Compl. ¶ 1 (failing to allege that Radcliffe is as an original source or that May provided the required information to the government). To qualify as an original source under the prior statute, a relator must have "direct and independent knowledge of the information on which the allegations are based and … [have] voluntarily provided that information to the government before filing[.]" 31 U.S.C. § 3730(e)(4)(B) (as previously codified). A relator's knowledge is "direct" if he "acquired it through his own efforts, without an intervening agency," and "independent" if "the knowledge is not dependent on a public disclosure." *U.S. ex rel Grayson v. Advanced Mgmt. Tech., Inc.*, 221 F.3d 580, 583 (4th Cir. 2000). To carry their pleading burden, a relator must "'allege specific facts—as opposed to mere conclusions—showing exactly how and when he or she obtained direct and independent knowledge of the fraudulent acts alleged in the complaint and support those allegations with competent proof.'" *U.S. ex rel. Black v. Health & Hosp. Corp. of Marion County*, 2011 WL 1161737, at *9 (D. Md. Mar. 28, 2011) (quoting *U.S. ex rel. Hafter v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1162 (10th Cir. 1999)).

Relators cannot meet this burden here. First, their jurisdictional allegations are entirely conclusory. *See* Compl. ¶ 1. Second, neither relator had any direct, personal knowledge of Purdue's practices during the limitations period, as Steven May left the company six years before filing this action, and Angela Radcliffe does not allege she ever had direct knowledge. *See* Section I.A & n.12 (discussing *Rockwell*, 549 U.S. at 475). In fact, May concedes that he was

not aware of the alleged falsity of Purdue's marketing statements until *after* he left the company (Compl. ¶ 23), meaning his knowledge could not be "direct" under the FCA. *See U.S. ex rel. Devlin v. State of Cal.*, 84 F.3d 358, 361 (9th Cir. 1996) ("In this case, the relators' knowledge was not direct and independent because they did not discover firsthand the information underlying their allegations of fraud. They did not see the fraud with their own eyes or obtain their knowledge of it through their own labor unmediated by anything else, but derived it secondhand from [someone else]."); *see also Minn. Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1042-1043 (8th Cir. 2002) (direct knowledge must be "unmediated by anything but [the relator's] own labor").

C. Dismissal Under State Public Disclosure Bars

Each of the state statutes under which May and Radcliffe bring their complaint contain similar jurisdictional limitations to those found in the FCA.[14] Relators' state causes of action should thus be dismissed for the same jurisdictional reasons as their federal counterpart.

III. THE COMPLAINT MUST BE DISMISSED FOR FAILURE TO PLEAD FRAUD WITH RULE 9(B) PARTICULARITY OR SATISFY THE BASIC PLEADING REQUIREMENTS OF RULE 8

A. The Complaint Fails To Satisfy Rule 9(b)

Rule 9(b) "plays an especially important role in the context of FCA *qui tam* actions." *U.S. ex rel. Owens v. First Kuwaiti Gen'l Trading & Contracting Co.*, 612 F.3d 724, 731 (4th Cir. 2010). This is because relators have suffered no injury of their own and may be "particularly likely" to file suits as a pretext for discovery, *id.* at 732, and "[t]he clear intent of Rule 9(b) is to eliminate fraud actions in which all the facts are learned through discovery after the complaint is filed." *Harrison v. Westinghouse Savannah Riv. Co.*, 176 F.3d 776, 790 (4th

[14] *See* Cal. Gov't Code § 12652(d)(3); Ga. Code Ann. § 49-4-168.2(j)(2); 740 Ill. Comp. Stat. 175/4(e)(4); N.Y. State Fin. Law § 190(9)(b); Tenn. Code Ann. § 71-5-183(e)(2)(A).

Cir. 1999). Accordingly, in the FCA context, courts strictly enforce Rule 9(b) by requiring relators, at a minimum, to identify "characteristic examples that are illustrative of the claims" upon which they seek to recover. *U.S. ex rel. Bledsoe v. Community Health Systems, Inc.*, 501 F.3d 493, 511 (6th Cir. 2007); *see also Chesbrough v. VPA, P.C.*, 655 F.3d 461, 470 (6th Cir. 2011) ("Although the relator does not need to identify *every* false claim submitted for payment, he must identify with specificity characteristic examples that are illustrative of the class of all claims covered by the fraudulent scheme." (quoting *Bledsoe*)).[15] Moreover, as the district court made clear in dismissing *Qui Tam 1*, the claims pled with 9(b) particularity must have been submitted within the FCA's six-year statutory limitations period. 2009 WL 161003, at *1; *see also U.S. ex rel. Sanders v. North Am. Bus. Indus., Inc.*, 546 F.3d 288, 296 n.3 (4th Cir. 2008) (requiring relators to allege "FCA violations within the statutory period with the particularity required by Federal Rule of Civil Procedure 9(b).")

This focus on false or fraudulent claims that were *actually* submitted to the government for payment is imperative because "the submission of a false claim is "the *sine qua non* of a False Claims Act violation." *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009). "Improper practices standing alone are insufficient to state a claim under either § 3729(a)(1) or (a)(2) absent allegations that a specific fraudulent claim was in fact submitted to

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[15] *See also U.S. ex rel. Sikkenga v. Regence BlueCross BlueShield*, 472 F.3d 702, 727 (10th Cir. 2006) ("[A relator must provide details that identify particular false claims for payment that were submitted to the government."]); *U.S. ex rel. Clausen v. Lab Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) ("[I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government."); *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 233 (1st Cir. 2004) (FCA complaint that "never specifies the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement," "provides no identification numbers or amounts charged in individual claims," and "does not identify or describe the individuals involved in the improper billing or allege with particularity any certification of compliance with federal regulations in order to obtain payments" subject to dismissal).

the government." *Id.*; *see also Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) ("[T]he False Claims Act at least requires the presence of a claim—a call upon the government fisc—for liability to attach.").

Here, as in *Qui Tam 1*, relators seek to bring a massive FCA case challenging *every* prescription of OxyContin covered by the federal and certain state healthcare programs over more than a decade. *See* Compl. ¶ 32 ("Each OxyContin prescription paid for by Medicaid constituted a false or fraudulent claim to the Government[.]"), ¶ 34 (seeking recovery from 1996 to 2009). Yet they cannot identify *even a single prescription*, much less a *characteristic set* of prescriptions indicating that a multi-year, nationwide fraud on the government took place. Their failure to do so requires dismissal, just as it did in *Qui Tam 1*. *See* 582 F. Supp. 2d at 784; 2009 WL 161003, at *1 (dismissing case because, even after four opportunities to amend, the relator could "not describe even a single instance in which a physician was influenced to prescribe OxyContin based on Purdue's [alleged] misrepresentations, and where a claim for payment was made by the pharmacist to the government.").

Enforcement of Rule 9(b) is critical here, because there is no uniform practice in prescribing OxyContin; each prescription of OxyContin is not representative of every other. As relators fully acknowledge, "it is well known in the medical community [that] a pain reliever's effectiveness will vary from individual to individual and the dosage has to be titrated [i.e., adjusted] for each patient." Compl. ¶ 12. In other words, *according to relators*, a doctor prescribing OxyContin will tailor the dosage to suit the pain-relief needs of each individual patient rather than apply a fixed equianalgesic ratio. Thus, one cannot simply assume that statements about the equianalgesic ratio between OxyContin and MS Contin factor into any doctor's decision to prescribe OxyContin—or the government's subsequent decision to pay for it. In fact, in *Qui Tam 1*, the complaint identified numerous doctors who rejected the 2:1 ratio

out-of-hand and *never* prescribed OxyContin on that basis, while others affirmatively prescribed it for unrelated reasons (e.g., because of their patients' inability to "tolerate MS Contin or other less expensive medications"). *Qui Tam 1* Compl. ¶ 16. Furthermore, once a doctor acquires first-hand familiarity with OxyContin, common sense dictates that he/she will rely on that first-hand experience (rather than marketing statements inconsistent with that experience) in prescribing pain-relief medications for future patients.

Relators' complaint falls well short of the Rule 9(b) standard. It fails to identify a single doctor who was induced (even once) to prescribe OxyContin by Purdue's alleged statements about its cost and potency relative to MS Contin—much less a doctor whose prescriptions, so induced, were then submitted to the government for reimbursement. Relators' assertion that identifying specific false claims "is neither feasible, nor practical" (Compl. ¶ 34) is contradicted by the record in *Qui Tam 1*. As his lawyers (the same lawyers representing relators here) told the district court in the prior case, they had attached to the complaint what they claimed was a list of "individual and unique prescriptions for OxyContin issued by [a doctor] each of which constitute a false or fraudulent claim that was submitted to and paid by Medicaid." Opp. to Mot. to Dismiss Fourth Am. Compl. 3, No. 1:05-cv-00089 (W.D. Va. Dec. 10, 2008).[16]

B. The Complaint Fails to Satisfy Rule 8

In addition to the Complaint's Rule 9(b) defects, it also fails even the more basic pleading requirements of Rule 8 because it does not allege any facts supporting the required elements of an FCA violation. To establish FCA liability, relators must demonstrate that: (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit

[16] As Purdue explained in *Qui Tam 1*, the list was unsupported by the complaint itself, and the case was dismissed for the reasons discussed above. 2009 WL 161003, at *1-*2.

moneys due (*i.e.*, that involved a 'claim')." *Harrison*, 176 F.3d at 788. The Supreme Court has made clear that a complaint must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Yet the present complaint consists of precisely "the formulaic recitation of the elements of a cause of action" that the Supreme Court deems insufficient.

In particular, the Complaint's allegations regarding the third and fourth elements of an FCA violation—materiality and causation—are entirely conclusory. *See, e.g.* Compl. ¶¶ 29, 33 (materiality), ¶¶ 20-22 (causation). Under the FCA, materiality is defined as "having a natural tendency to influence, or be capable of influencing, *the payment or receipt of money or property*." 31 U.S.C. § 3729(b)(4) (emphasis added). Relators assert that Purdue's statements regarding the relative potency and cost of OxyContin are actionable because "the government did not get the benefit of its bargain," (Compl. ¶ 33), but there is no basis from which to assume that a doctor's initial dosing of OxyContin (or its cost relative to MS Contin) was material to the government's decision to pay. In other words, the government's decision to reimburse a Medicare prescription may have been based entirely on whether an authorized pharmacy submitted a valid prescription by a licensed doctor. The complaint asserts no facts to the contrary. Courts have held that dismissal is required for precisely this reason. *See, e.g., U.S. ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, No. 1:09-cv-1086, 2011 WL 2182422, at *4 (May 4, 2011 E.D. Va. 2011) (dismissing FCA case involving drug company's marketing statements for failure to plead their materiality to government payment). As the court explained in dismissing *Takeda*: "Relator has failed to plead materiality because … Relator has not identified the criteria by which the relevant governmental agencies decide whether to provide reimbursement benefits for a prescription. Without knowing what those criteria may be, this Court is unable to conclude

... that any alleged statements by Takeda had a natural tendency to influence agency action or were capable of influencing agency action." *Id.* Dismissal is similarly warranted here.

With respect to causation, the allegations consist of assertions that Purdue's marketing was "successful[]." *See, e.g.,* Compl. ¶ 20 (May and others "successfully marketed" OxyContin to doctors over unspecified time period), ¶ 21 (similar, with respect to institutions); ¶ 22 (similar, with respect to Virginia VAMC, but outside of the six-year limitations period); *cf.* ¶ 24 (alleging further institutional marketing, but no resulting purchases). These allegations fail to establish that, within the six-year limitations period relevant to this action, Purdue's alleged misrepresentations "caused the government to pay out money or to forfeit moneys due." *Harrison*, 176 F.3d at 788.

In the context of OxyContin—a widely prescribed, FDA-approved pain medication—there is no basis to assume that doctor's prescriptions or the government's payments for them were caused by Purdue's marketing statements regarding the medication's potency and cost relative to the particular "benchmark" (Compl. ¶ 12) that relators have made the focus of their complaint. It is equally if not more plausible that OxyContin was prescribed—and purchased—for reasons entirely independent of its relative cost and potency vis-à-vis the MS Contin "benchmark." As noted above, relators agree that any doctor prescribing OxyContin would tailor the dose of the medication to the needs of each patient—a medical decision independent of Purdue's alleged marketing statements. As with materiality, relators cannot simply assume the element of causation, but must allege sufficient facts to establish it in the face of alternative explanations to the contrary. *See Iqbal*, 129 S. Ct. at 1950, 1952 (in considering plausibility of complaint, court may consider "obvious alternative explanation[s]," drawing on its own "judicial experience" and "common sense" (internal quotation marks omitted)). Where, as here, a relator fails to do so, dismissal is warranted. *See, e.g. Takeda*, 2011 WL 2182422, at *4 ("Relator's

failure to identify the criteria for reimbursement and describe the process through which reimbursement may be sought prevents the Court from concluding that Relator has adequately alleged that any false records or statements attributable to Takeda *caused* the government to pay for improper reimbursements." (emphasis added)).

IV. THE STATUTE OF LIMITATIONS BARS RECOVERY ON ALL BUT A HANDFUL OF RELATORS' CLAIMS

In the event the Court does not dismiss the entire Complaint under Rules 8 or 9(b), it must at least limit this action to the six-year statutory limitations period. *See Sanders*, 546 F.3d at 293. Applying this bar, there can be no recovery for claims before December 30, 2004.[17] Further, to survive dismissal, relators must identify "characteristic examples" of prescriptions submitted for government reimbursement after May left Purdue based on marketing statements made while he was employed there. Relators have failed to do so. *See supra* III.A.

V. THE COURT SHOULD DISMISS OR DECLINE TO EXERCISE SUPPLEMENTAL JURISDICTION OVER THE STATE LAW CLAIMS

Because relators' only federal claim must be dismissed for the reasons stated above, Purdue respectfully suggests that the Court decline to exercise supplemental jurisdiction over relators' remaining state law claims. *See* 28 U.S.C. § 1367(c)(3); *A.T. Massey Coal Co. v. Meadows*, 476 F. Supp. 2d 578, 584 (S.D. W. Va. 2007).

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[17] The FCA statutes of Georgia, Illinois, and Tennessee contain virtually identical limitations periods (Ga. Code Ann. § 49-4-168.5; 740 Ill. Comp. Stat. 175/5(b); Tenn. Code Ann. § 71-5-184(b)(1)); thus, relators' state law claims preceding December 30, 2004 must be dismissed as well. Additionally, California's FCA statute provides that, "A civil action under Section 12652 may not be filed more than three years after the date of discovery by the Attorney General or prosecuting authority with jurisdiction to act … or, in any event, not more than 10 years after the date on which the violation of Section 12651 was committed." Cal. Gov't Code § 12654(a). California was named as a party in *Qui Tam 1*. Applying a three-year limitations period from the date that action was filed requires dismissal of any claims preceding September 27, 2005. Finally, New York provides for a ten-year limitations period, N.Y. State Fin. Law § 192, requiring, at minimum, dismissal of any claims preceding December 30, 2000.

In any event, the state law claims must also be dismissed because of relators' failure to comply with state procedural requirements. Each state requires that a copy of the complaint and written disclosure of substantially all relators' material evidence be served on particular state officials in accordance with that state's rules of procedure.[18] There is no evidence that relators have complied with these procedures. Further, California expressly requires that "[a] complaint filed by a private person under this subdivision *shall be* filed in superior court in camera." Cal. Gov't Code § 12652(c)(2). These defects require dismissal of relators' Complaint.

Assuming relators' procedural defects could be cured (and they cannot), in order to avoid dismissal, relators must plead violations of each state statute in a manner that satisfies Rule 9(b) and/or Rule 8. For the reasons stated above, relators have failed to do so. Remarkably, relators do not identify a single doctor, institution, or prescription in either New York or Tennessee—two of the five states on whose behalf they seek to recover—and the allegations with respect to the other three states are entirely conclusory. Relators' state law claims should thus be dismissed. *See Radcliffe*, 2009 WL 161003, at *2 (dismissing state claims where "he has not identified with particularity any misrepresentations in those states").

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[18] Cal Gov't Code § 12652(c)(3) ("On the same day as the complaint is filed … the qui tam plaintiff shall serve by mail with 'return receipt requested' the Attorney General with a copy of the complaint and a written disclosure of substantially all material evidence") & § 12656(a)-(b) (individual who commences a proceeding must "serve a copy of the notice or petition initiating the proceeding … within three days of the filing, on the Attorney General" with compliance serving as a "jurisdictional prerequisite"); Ga. Code Ann. § 49-4-168.2(c)(1) (copy of complaint and written disclosure of substantially all material evidence "shall be served on the Attorney General"); 740 Ill. Comp. Stat. 175/4(b)(2) (copy of complaint and written disclosure of substantially all material evidence "shall be served on the State"); Tenn. Code Ann. § 71-5-183(b)(2) (same); N.Y. State Fin. Law § 190(2)(b) (requiring personal service of complaint and substantially all material evidence upon the state).

CONCLUSION

The Court should dismiss relators' Complaint with prejudice and grant Purdue such other relief as the Court deems just and equitable.

Dated: February 9, 2012

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
BECKLEY

United States of America *et al.*,
ex rel. Steven May and
Angela Radcliffe,

Plaintiffs,

v.

Civil Action No. 5:10-1423
(Honorable Irene C. Berger)

Purdue Pharma L.P. and Purdue
Pharma Inc.,

Defendants.

CERTIFICATE OF SERVICE

I, Rebecca A. Betts, counsel for defendants Purdue Pharma L.P. and Purdue Pharma Inc., hereby certify that on the 9th day of February, 2012, I electronically filed "Defendants Purdue Pharma L.P. and Purdue Pharma Inc.'s Memorandum in Support of Motion to Dismiss" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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